

been made to provide proper headings for the Specification. In addition, claims 1-12 have been amended and new claim 13 added in an effort overcome the objections and rejections set forth by the Examiner in the initial office action.

Claims 1-8 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. In this respect, the Examiner had questioned the use of the term "oily material" as well as other words in the claims. The claims have been amended to overcome this grounds for rejection. The "oily material" is now defined as an oily non-polar lipid material. The support for this amendment is found in the original specification beginning at page 4, line 28. It is believed that the term now utilized in the claims finds support in the specification such that it would be clear to one of ordinary skill in the art what is referenced in the claim language. In view of the foregoing, reconsideration of the grounds for rejection under 35 U.S.C. 112, second paragraph, is respectfully requested.

Claims 1-12 have been rejected under 35 U.S.C. 101 in view of the objection under 35 U.S.C. 112, second paragraph. In this respect the amendment to the claims is believed to overcome this grounds for rejection and, therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. 101 is respectfully solicited.

It should be noted that the claims have been amended to provide proper method steps, especially with respect to the

amendment to claim 1. It is respectfully submitted that claim 1 defines a method for prolonging the local effect of a topically applied active substance such as a pharmaceutical or cosmetic by providing for steps to blend such pharmaceutical or cosmetic with an oil-in-water emulsifier which is prepared to include a non-polar lipid oily material, an aqueous phase, and a galactolipid material as the emulsifier.

Claims 1-7 and 9, 10 have been rejected under 35 U.S.C. 102(b) as being directly anticipated by Carlsson et al., WO 95/20943. Claims 1-11 have also been rejected under 35 U.S.C. 103(a) as being obvious and therefore unpatentable over Carlsson, as well as unpatentable over Carlsson when considered in combination with the reference to Yamada et al., US Patent 5,885,978. Claim 12 has also been rejected under 35 U.S.C. 103(a) as being obvious and therefore unpatentable over Carlsson et al. when considered in view of the teachings of the reference to Horrobin, US Patent 4,444,755. For the reasons set forth below, reconsideration of the grounds for rejection over the art is respectfully solicited.

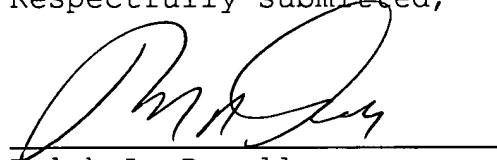
The reference to Carlsson, WO 95/20943, describes a galactolipid material which is used in the present invention. It should be noted, however, that nothing in the cited reference is stated about prolonging the effective properties of active substances in a pharmaceutical or cosmetic-type material. It is the use of galactolipid materials to provide for a new use in

prolonging the effect of pharmaceuticals and cosmetics which is novel with respect to the present invention. Nothing in the primary reference to Carlsson et al. nor the secondary references to Yamada and Horrobin discloses that galactolipid materials can be used as a prolonging agent to extend the effective life of cosmetics and pharmaceuticals found in lotions and creams which are topically applied. Thus, the invention is directed to a new use for a known substance.

As the prior art does not recognize the benefits which can be obtained to extend the effective life of active substances including pharmaceuticals and cosmetics used in topical creams and lotions, it is respectfully submitted that the application defines an invention which is novel and not anticipated by the prior art references taken alone or in combination.

In view of the foregoing, reconsideration of the grounds for rejections under both 35 U.S.C. 102(b) and 35 U.S.C. 103(a) is respectfully solicited and favorable consideration and allowance of claims 1-13 requested. An earnest effort has been made to place this application in condition for allowance. Should the Examiner have any questions concerning this response or the amendments submitted herewith, it would appreciated if the Examiner would contact the undersigned attorney of record at the telephone number below for further expediting the prosecution of the application.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) [Use of a formulation of the oil-in-water emulsion type comprising an oily material, an aqueous phase and a galactolipid material as an emulsifier, as a carrier for the preparation of a topical cream or lotion providing a prolonged local effect of an incorporated pharmaceutically or cosmetically active substance.] A method of prolonging a local effect of a pharmaceutically or cosmetically active substance when such substance is used in a topical cream or lotion, the method comprising:
  - a. providing an oil-in-water emulsion carrier including an oily non-polar lipid material, an aqueous phase and a galactolipid material as an emulsifier;
  - b. adding a pharmaceutically or cosmetically active substance to the carrier to form a formulation for a topical cream or lotion; and
  - c. wherein the galactolipid material is present in the formulation for a topical cream or lotion in an amount to prolong a local effect of the active substance when the topical cream or lotion is topically applied.

2. (Amended) [Use] The method according to claim 1,

wherein [the formulation comprises] 0.1-50% by weight of oily material and 0.5-20% by weight of emulsifier are provided in the formulation.

3. (Amended) [Use] The method according to claim 1, wherein [the formulation comprises] 1-40% by weight of oily material and 0.5-10% by weight of emulsifier are provided in the formulation.

4. (Amended) [Use] The method according to claim 1, [wherein] including providing the galactolipid material so as to consist[s] of at least 50% by weight of digalactosyldiacylglycerols and a remainder of [other] non-digalactosyldiacylglycerol polar lipids, and adding the galactolipid material so as to constitute[s] an amount of 1.0-5.0% by weight of the formulation.

5. (Amended) [Use] The method according to claim 1, [wherein] including providing the galactolipid material so as to consist[s] of 50-70% by weight of digalactosyldiacylglycerols and 30-50% by weight of [other] non-digalactosyldiacylglycerol polar lipids.

6. (Amended) [Use] The method according to claim 1,  
[wherein] including providing the galactolipid material [is] as a  
fractionated oat oil which consists of at least 15% by weight of  
digalactosyldiacylglycerols and a remainder of [other] non-  
digalactosyldiacylglycerol polar and non-polar lipids, and adding  
the galactolipid material so as to constitute[s] an amount of  
2.0-10% by weight of the formulation.

7. (Amended) The method according to claim 6, [wherein]  
including providing the galactolipid material [is] as a  
fractionated oat oil which contains 40-60% by weight polar lipids  
and a remainder of non-polar lipids.

8. (Amended) [Use] The method according to claim 1[, of]  
wherein the oil-in-water emulsion is formed as a cream base by  
providing [comprising,] in % by weight;

Oily <u>non-polar lipid</u>	10.0-30.0%
Galactolipid emulsifier	0.5-5%
Thickner	2.0-10.0%
Preservative	0.1-1.0%
Water	ad 100%

9. (Amended) [Use] The method according to claim 1

including [for the preparation of a topical cream or lotion,] incorporating a moisturizer [moisturiser, especially glycerol,] as the active substance.

10. (Amended) [Use] The method according to claim 1 [for the preparation of a medicament for prophylaxis or] including adding an active substance for use in treatment of atopic dermatitis.

11. (Amended) [Use] The method according to claim 1 [for the preparation of a topical cream or lotion,] including incorporating a corticosteroid as the active substance, for treatment of skin inflammation.

12. (Amended) [Use] The method according to claim 1[, for the preparation of a topical anti-psoriatic cream or lotion,] including incorporating 13-hydroxy-linoleic acid as the active substance.